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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/061,835	01/31/2002	Frank J. Landherr	112713-115	9493
29200	7590	07/20/2004	EXAMINER	
BAXTER HEALTHCARE CORPORATION RENAL DIVISION 1 BAXTER PARKWAY DF3-3E DEERFIELD, IL 60015			HARAN, JOHN T	
			ART UNIT	PAPER NUMBER
			1733	
DATE MAILED: 07/20/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/061,835

Applicant(s)

LANDHERR ET AL.

Examiner

John T. Haran

Art Unit

1733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-100 is/are pending in the application.
- 4a) Of the above claim(s) 1-14, 47-86, 88, 93 and 94 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30-46 is/are allowed.
- 6) ☒ Claim(s) 15, 17, 18, 20-29, 87, 90-92, and 97-100 is/are rejected.
- 7) ☒ Claim(s) 19, 95 and 96 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/28/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

1. Newly submitted claims 93 and 94 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: new claims 93 and 94 are directed to nonelected group IV drawn to a device for providing the disconnection of a flexible tube.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 93 and 94 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on 6/28/04 has been considered by the examiner.

It is noted that items A1-A72, B1-B17, and C1-C4 are struck through because they were previously considered.

It is noted that the following documents were struck through because no copy has been presented as required b7 37 CFR 1.98(a)(2):

FR1471450

JP72044977

JP46042639

JP75016826

CN 1052131

JP08295862

EP564231

WO9836902

WO9924242

BR9705844

JP2002146303

Search Report dated 7/5/02

It is also noted that the remainder of the foreign documents that are struck through is because there is no concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language, as required by 37 CFR 1.98(a)(3).

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 87 is rejected under 35 U.S.C. 102(b) as being anticipated by JP 53-14772.

JP 53-14772 is directed to a laser welding machine comprising a laser unit, a pair of tube holders each adapted to receive tube ends and urge them together after they

are heated with a laser beam to form a weld; and a prism (2) not positioned between the pair of tube holders that directs the laser beam to strike the tube ends (See Figure 3-4 and English abstract). JP 53-14772 anticipates claim 87.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 15, 18, 20, 21, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivansons et al (U.S. Patent 5,279,685) in view of Kagan (Infrared welding technology and developed materials for a new era, June 11-13, 2001).

Ivansons et al is directed to a device used for the connection of a plastic tube comprising a pair of tube holders adapted to receive flexible tube ends and adapted to urge the two tube ends together after the two tube ends have been heated to join the heated tube ends together to form a weld and a heated wafer for insertion between two spaced apart tube ends held in the tube holders for heating the tube ends (Figure 15 and Column 8, lines 54-62). Ivansons et al is silent towards using a laser beam to heat the ends of the plastic tubes.

One skilled in the art would have readily appreciated that welding devices that use laser beams to heat plastic parts for welding them together are well known and

conventional as shown for example in Kagan. Kagan teaches welding two plastic parts together with a laser optics assembly wherein the plastic parts are spaced apart, a prism (mirror) is placed in between and a laser beam is directed towards the prism which redirects the laser beam to the two plastic parts, then the prism is removed from between the plastic parts, and the plastic parts are brought together to form a weld (See Figure 1). One skilled in the art would have readily appreciated that the prism would either be moved by machine or by hand and it would have been obvious to have it movably mounted on a machine. One skilled in the art would have readily appreciated that a heating wafer and a laser optics assembly are alternate expedients for heating that are obvious over one another. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a laser beam as the heating implement in the device of Ivansons et al because as suggested in Kagan lasers with an optics assembly such as a movably mounted prism that redirects the laser beam are known heating implements for welding plastic parts and are an alternate expedient to a heating wafer.

Regarding claim 18, one skilled in the art would have readily appreciated that the prism would either be moved by hand or by an apparatus and it would have been obvious to use an apparatus.

Regarding claim 20, one skilled in the art would have readily appreciated that the laser is capable of sufficiently heating the tubes ends to sterilize them.

Regarding claim 21, Kagan teaches the prism changes the plane of the laser (See Figure 1).

Regarding claim 24, one skilled in the art would have readily appreciated that the device of Ivansons et al, as modified above, is capable of exerting sufficient heat and pressure to obtain a hermetic seal.

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ivansons et al (U.S. Patent 5,279,685) in view of Kagan (Infrared welding technology and developed materials for a new era, June 11-13, 2001) as applied to claim 17 above, and further in view of Emmelmann (U.S. Patent 6,201,211).

Regarding claim 17, Kagan is silent towards having a collimator located between the laser unit and the prism, however such is well known and conventional in the laser optics art as shown for example in Emmelmann (See Figure 4). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include conventional components in the laser optics assembly, such as a collimator located between the laser unit and prism, in the device of Ivansons et al, as modified above.

8. Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivansons et al (U.S. Patent 5,279,685) in view of Kagan (Infrared welding technology and developed materials for a new era, June 11-13, 2001) as applied to claim 17 above, and further in view of Savitski et al (U.S. Patent 6,596,122).

Regarding claims 22 and 23, Kagan is silent towards have a y-shaped light guide, however it is well known and conventional to use light pipes to direct laser beams as shown for example in Savitski et al (Column 6, line 47). One skilled in the art would

have been motivated to use a y-shaped light guide to split the laser beam to either tube end as an alternate expedient to the prism of Kagan. It would have been obvious to have a y-shaped light pipe in the device of Ivansons et al, as modified above.

9. Claims 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivansons et al (U.S. Patent 5,279,685) in view of Giragosian et al (U.S. Patent 5,592,078) and Kagan (Infrared welding technology and developed materials for a new era, June 11-13, 2001).

Ivansons et al is directed to a device of the connection of plastic tube comprising a pair of tube holders adapted to receive a flexible tube end and adapted to urge the two tube ends together after the two tube ends have heated to join the heated tube ends together to form a weld and a heated wafer for insertion between two spaced apart tube ends held in the tube holders for heating the tube ends (Figure 15 and Column 8, lines 54-62). Ivansons et al is silent towards having a sensor for analyzing the connection between the tube ends.

One skilled in the art would have readily appreciated that a perfect weld is desired without any leaks or imperfections when welding tube ends because the purpose of a tube is to have liquid flow through it and it is undesirable to have leaks. One skilled in the art would have readily appreciated performing a visual inspection or having a sensor for doing the same. Furthermore it is known to have sensors for analyzing the connection, as shown for example in Giragosian (Column 5, lines 11-21). Additionally Ivansons et al teaches having clamp sensors for ensuring the clamps of the



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tube holders are closed and the tubes are in the clamps, a controller for testing that the tubes are correctly loaded and positioned in the clamp holders, thermocouples for monitoring the temperature, and a controller for monitoring the time the tube ends are held together to ensure adequate welding, but is silent towards having a sensor for analyzing the connection (Column 7, line 61 to Column 8, line 27). One skilled in the art would have readily appreciated that all the sensors and controls taught in Ivansons et al are directed towards ensuring an adequate weld between the tube ends and would have been motivated to include an additional sensor to analyze the connection as an additional check, as suggested in Giragosian. It would have been obvious to one of ordinary skill in the art at the time the invention was made to one of ordinary skill in the art at the time the invention was made to include a sensor to analyze the connection of the two tube ends in order to additionally ensure an adequate weld as suggested in Giragosian.

Ivansons et al is also silent towards using a laser beam to heat the ends of the plastic tubes. One skilled in the art would have readily appreciated that welding devices that use laser beams to heat plastic parts for welding them together are well known and conventional as shown for example in Kagan. Kagan teaches welding two plastic parts together with a laser optics assembly wherein the plastic parts are spaced apart, a prism (mirror) is placed in between and a laser beam is directed towards the prism which redirects the laser beam to the two plastic parts, then the prism is removed from between the plastic parts, and the plastic parts are brought together to form a weld (See Figure 1). One skilled in the art would have readily appreciated that a heating wafer

and a laser optics assembly are alternate expedients for heating that are obvious over one another. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a laser beam as the heating implement in the device of Ivansons et al, as modified above to have a sensor for analyzing the connection, because as suggested in Kagan lasers are known heating implements for welding plastic parts and are an alternate expedient to a heating wafer.

Regarding claims 26-28, as noted above Ivansons et al teaches a tracking system for moving the two tube holders together, a positioning detector for the tubes and heat sensor for monitoring the temperature.

Regarding claim 29, Kagan teaches the optics assembly directs the laser to the tube ends.

Regarding claim 89, Giragosian teaches using a weld inspection sensor (Column 5, lines 11-21).

Regarding claims 90 and 91, one skilled in the art would have readily appreciated that a weld inspection sensor would analyze the weld thickness and height and compare it to compiled data to ensure it meets the desired specifications. It would have been obvious to use such a sensor in the device of Ivansons et al, as modified above.

Regarding claim 92, such sensors are taken as being well known and conventional and it would have been obvious to use conventional sensors in the device of Ivansons et al, as modified above.

10. Claims 97-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 53-14772.

JP 53-14772 is relied upon for the teachings note above in regards to claim 87.

Regarding claims 97-99, JP 53-14772 is silent towards the type of lens utilized however they are well known and conventional lens and it would have been obvious to one of ordinary skill in the art at the time the invention was made to use conventional lens in the device of JP 53-14772.

Regarding claim 100, it is well known and conventional to have an additional lens located between the tube ends and the prism for focusing the beam and it would have been obvious to include such in the device of JP 53-14772.

### ***Response to Arguments***

11. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Allowable Subject Matter***

12. Claims 19, 95 and 96 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 19, the prior art of record fails to suggest the claimed device for providing a connection between two flexible tube ends, particularly having a prism for reflect the laser beam to heat the two tube ends and a light pipe for directing the laser beam to weld the two tube ends together.

There is no suggestion or motivation in the art of record for having a prism and a light guide for directing a laser beam while heating and welding.

Regarding claims 95 and 96, the prior art of record fails to suggest the claimed device for providing a connection between two flexible tube ends, particularly including a protective film around the laser optics assembly or the prism.

There is no suggestion or motivation in the art of record for having such a protective film around the prism or laser optics assembly.

14. Claims 30-46 are allowed.

15. The following is an examiner's statement of reasons for allowance:

The prior art of record fails to suggest the claimed device for providing a sterile connection between two flexible tube ends, particularly having a housing with slots adapted for receiving tube ends and a pair of guides positioned within the housing.

JP 6-91010 is directed to a device for aseptic splicing of flexible tubes wherein the device uses a heat wafer to heat tube ends and tube holders bring the tube ends together to form a weld and the device is contained within a housing (See Figure 2). There is no suggestion or motivation for the housing having slots on the sides for receiving tubes because it appears the operation is done with the lid of the housing

open and the tubes are manually placed in the tube holders so there is no need for guides.

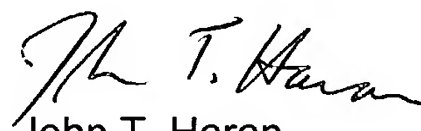
16. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **John T. Haran** whose telephone number is **(571) 272-1217**. The examiner can normally be reached on M-Th (8 - 5) and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Blaine Copenheaver can be reached on (571) 272-1156. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
John T. Haran  
Examiner  
Art Unit 1733